DHS IRB
PROCEDURES MANUAL

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UTAH DEPARTMENT OF HUMAN SERVICES
INSTITUTIONAL REVIEW BOARD

PROCEDURES

This document provides the procedures followed by the Utah Department of Human Services Institutional Review Board (DHS IRB) in the review and approval process for research involving human subjects. The appropriate Federal regulatory citations are included in parentheses. Unless otherwise noted, citations are from 45 CFR 46, Federal Policy for the Protection of Human Subjects.

CONVENED MEETINGS

The DHS IRB meets monthly to review research protocols involving human subjects. A majority of IRB members, including one nonscientist, must be present for a quorum. The meeting is suspended any time the number of members present is less than a majority, or if there is no nonscientist present.[1] The National Committee for Quality Assurance (NCQA) has provided guidance regarding who may be considered a nonscientist. NCQA defines a nonscientist as a member without scientific training or experience, such as lawyers, clergy and ethicists. Retired scientists, by NCQA definition, are not considered nonscientific members. Further, scientific members include physicians, dentists, Ph.D. scientists, pharmacists, nurses, veterinarians and others with scientific training and experience. Members with a combination of both scientific and nonscientific backgrounds should not be appointed to satisfy the nonscientist requirement. The member representing prisoners must be present at any meeting considering research involving prisoners (§46.304). For all biomedical protocols, the DHS IRB uses a nonvoting member who is a physician. The physician must be present for, and an active participant in, the review of all biomedical protocols.

Monthly meetings are scheduled in advance annually. The monthly meeting may be cancelled due to lack of quorum, or lack of agenda items. One week prior to the meeting the IRB Chair, or designee, distributes all protocols to all members for review. On occasion, it may be necessary to hand deliver or overnight mail meeting packets to ensure sufficient time for review.

Special meetings may be called between monthly meetings when the monthly meeting falls after an important deadline date or there is a quorum issue. An

[1] Unless the research under review qualifies for expedited review, pursuant to § 46.110.

important deadline date may include a funding submission deadline or an approval expiration date for either DHS or any other institutional IRB. If the nonvoting physician member and/or prisoner representative cannot attend a monthly meeting at which they are needed, a special convened meeting may be called to accommodate their schedules to review the protocol. The regularly scheduled monthly meeting will be held as scheduled to review all other protocols.

In the event a special meeting is necessary, the IRB Chair, or designee, contacts every IRB member by phone or email to determine availability and to ensure a proper quorum for the convened meeting. Following assurance of a quorum, the IRB Chair, or designee, notifies each member of the time, date, and place for the meeting. The protocol(s) to be reviewed may be distributed by hand or overnight mail to ensure sufficient time for review by every member.

Utah's Open Meetings Law

The DHS IRB is subject to the Utah Open and Public Meetings Law (*U.C.A.* § 52-4-1 through 7). Notice of regularly scheduled meetings are publicized through posting on the DHS website, posting written notice at the principal office of the DHS in Salt Lake City, and providing notice to at least one newspaper of general circulation within Salt Lake City, or to a local media correspondent. Notice of regular meetings is provided at least once per year, specifying the date, time, and place of the meeting. In addition, public notice of all regular meetings will be made not less than 24 hours prior to the meeting and will include agenda, date, time and place of the meeting.

RESEARCH REVIEW MATERIALS

Initial Review Materials

In conducting the initial review of proposed research, the IRB must obtain information in sufficient detail to make the determinations required under §46.111. Materials should include the full protocol, a proposed informed consent document, any relevant grant application(s), as per §46.103(f), the investigator's brochure (if one exists), any surveys, questionnaires or other materials to which potential subjects will be exposed, and any recruitment materials, including advertisements intended to be seen or heard by potential subjects. Furthermore, for US Department of Health and Human Services (DHHS)-supported multicenter clinical trials, the IRB should receive and review a copy of the DHHS-approved sample informed consent document and the complete DHHS-approved protocol, if they exist. The primary reviewer will receive a copy of the complete documentation, while all other members receive all but the Investigator's brochure.

Continuing Review Materials

Continuing review of research must be substantive and meaningful. The IRB will ensure that the criteria set forth by §46.111 are satisfied at the time of continuing review. In conducting continuing review of research not eligible for expedited review, all IRB members will at least receive and review a protocol summary and a status report on the progress of the research, including:

- the number of subjects accrued;
- a summary of adverse events and any unanticipated problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review;
- a summary of any relevant recent literature, interim findings, and amendments or modifications to the research since the last review;
- any relevant multi-center trial reports;
- any other relevant information, especially information about risks associated with the research; and
- a copy of the current informed consent document and any newly proposed consent document.

The primary reviewer will receive a copy of the complete protocol including any modifications previously approved by the IRB. Furthermore, upon request, any IRB members also should have access to the complete IRB protocol file and relevant IRB minutes prior to or during the convened IRB meeting.

Expedited Review Materials

When reviewing research under an expedited review procedure, the Division IRB Representative, IRB Chair, or designee, should receive and review all of the above-referenced documentation, including the complete protocol.

MINUTES

The minutes of each convened meeting are recorded and prepared by the Chair, or a designee, in accordance with §46.115(a)(2).

Documentation of Deliberations

The minutes of IRB meetings document separate deliberations, actions, and votes for each protocol undergoing initial or continuing review by the convened IRB. The basis for requiring changes in or disapproving research and a written summary of the discussion of controverted issues and their resolution will be included in the minutes.

Documentation of Findings: Informed Consent Waiver or Alteration

DHHS regulations at 45 CFR 46.116(d) require that the IRB make and document four findings when approving a consent procedure which does not include, or which alters, some or all of the required elements of informed consent or when waiving the requirement to obtain informed consent.

When approving such a waiver or alteration for research reviewed by the convened IRB, these findings will be documented in the minutes of the IRB meeting, including *protocol-specific* information justifying each IRB finding. The four findings in §46.116(d) are

- the research involves no more than minimal risk to the subjects;
- the waiver or alteration will not adversely affect the rights and welfare of the subjects;
- the research could not practicably be carried out without the waiver or alteration; and
- whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Documentation of Findings: Waiver of Documentation of Informed Consent

The regulations require that the IRB make and document which of two findings apply when approving a waiver of the requirement for obtaining a signed consent form. When approving such a waiver for research reviewed by the convened IRB, these findings will be documented in the minutes of the IRB meeting, including *protocol-specific* information justifying each IRB finding. These findings in §46.117(c) are

- that the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
- that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

Documentation of Findings: Other Required Findings

Similarly, where DHHS regulations require specific findings on the part of the IRB,

- approving research involving pregnant women, human fetuses, or neonates (§46.204-207);

- approving research involving prisoners (§46.305-306); or
- approving research involving children (§46.404-407),

the IRB should document such findings. For research approved by the convened IRB, all required findings will be fully documented in the minutes of the IRB meeting, including *protocol-specific* information justifying each IRB finding.

Expedited Review Findings

For research reviewed under an expedited review procedure, the IRB Chair or other designated reviewer elsewhere in the IRB record will document these findings.

Documentation of Risk and Approval Period

The IRB will determine which protocols require continuing review more often than annually, as appropriate to the degree of risk (§46.103(b)(4) and §46.109(e)). The minutes of IRB meetings will clearly reflect these determinations regarding risk and any approval period (review interval) of less than one year.

Documentation of Vote

The minutes include the vote on all IRB actions including the number of members voting for, against, and abstaining, using the following format: Total = 9; Vote: For-8, Opposed-0, Abstained-1.

Distribution

Draft minutes are mailed electronically to all members for review, additions or corrections, and approval. All members receive a copy of the final minutes. A copy of the final minutes is also sent to the Institutional Official, Mark E. Ward, Deputy Director, Department of Human Services.

ROLE OF DIVISION-LEVEL IRB MEMBER

The DHS IRB utilizes a system of “Gatekeepers.” Each gatekeeper is an IRB member and represents a Division of the DHS. Research protocols are submitted to the appropriate Division IRB Representative for Division approval for issues outside the IRB purview. These include issues such as use of resources (budgetary, space, staff), and appropriateness, such as whether the proposed research is in line with DHS Mission and Goals.

The Division IRB Representative will review the proposed research and make written findings that indicate whether:

- the research is in the best interests of the Division and the Division’s clients;

- the Researcher has made adequate provision for obtaining informed consent from the subjects or permission from the subjects' parents or legal guardian, and where applicable, informed assent from children or from clients who suffer from some mental incapacity;
- the research protocols and procedures are designed to protect individual privacy and ensure confidentiality, respect, and ethical treatment during the Researcher's gathering of the data, storage and retrieval of the data, and publication of the data;
- the research study involves no more than minimal risk to subjects, or if the risk is more than minimal, that the direct benefits to the human subjects outweigh the risks. (See Appendix A for minimal risk definition.);
- the research methodology is sufficiently sound to yield results that offer a potential benefit to the Department or the Division; and,
- the research protocol protects individual privacy rights, and complies with the Department's Vision and Mission Statements, the Department Code of Ethics and any applicable rules or statutes, including *Utah Code Annotated* § 63-2-202(8) (GRAMA).

If the Division IRB Representative finds that the proposed research satisfies these requirements, the Division IRB Representative prepares a written statement to this effect, and submits this statement to the Division Director for written approval. If the Division Director approves the research project, the Division IRB Representative sends a copy of the written findings and the Division's approval to the DHS IRB.

If the proposed research also requires the review and approval of the full DHS IRB, the Division IRB Representative notifies the DHS IRB of this requirement, and forwards the Researcher's application and supporting documentation to the DHS IRB for its review. If the research involves greater-than-minimal risk but no direct benefit to the human subjects, the Division IRB Representative notifies the Researcher and the DHS IRB in writing why the research does or does not qualify for Division approval under the section of the DHS IRB policies that deals with such studies.

PRIMARY REVIEWER SYSTEM

The DHS IRB utilizes a primary reviewer system. In this system, the Division IRB Representative presents the protocol to the IRB. The Division IRB Representative informs the appropriate Division management of the final IRB determination. The procedures are more fully explained below.

DISTRIBUTION OF DOCUMENTS FOR REVIEW

The Division IRB Representative provides the IRB Chair with sufficient copies of the protocol submission based on level of review.

Exempt Review

The Division IRB Representative provides the IRB Chair with the original submission for the file.

Expedited Review

The Division IRB Representative provides the IRB Chair with the original submission for the file.

Review at Convened Meeting

The Division IRB Representative provides the IRB Chair with the original submission for the file. The Division IRB Representative provides the IRB Chair with one copy of the entire submission, minus any investigator's brochures, for each IRB member. The IRB Chair distributes a copy of each protocol and the agenda to each IRB member one week prior to each regularly scheduled meeting. The IRB Chair distributes a copy of each protocol and the agenda to each IRB member one week prior to each special meeting, whenever possible. The IRB Chair will ensure there is sufficient time to review the materials prior to a special meeting.

IRB REVIEW

The IRB review system is shown schematically in the DHS IRB Policy statement. In some cases there are additional steps or requirements for research proposed by any Researcher who is not employed by the DHS IRB.

No IRB member may participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB (§46.107(e)).

INITIAL REVIEW

The Researcher submits the research protocol to the appropriate Division IRB Representative.

Review by the Division IRB Representative

The Division IRB Representative screens the protocol to determine if it involves human subjects research and if it is a project the Division will approve.

Is It Research?

Research is defined in 45 CFR 46: "*Research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities, which meet this definition, constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities." If it is not research, the Division IRB Representative notifies the Researcher and the IRB Chair of the determination.

Are Human Subjects Involved?

Human subjects are defined in 45 CFR 46: "*Human subject* means a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or identifiable private information." The complete definition is contained in Appendix A. If human subjects are not involved, the Division IRB Representative notifies the Researcher and the IRB Chair of the determination.

Is the Project Approvable by the Division?

While this is not an IRB function, by sending it through appropriate Division processes, the Division IRB Representative removes any protocol from the IRB process that the Division will not approve. The IRB will not review protocols that are not approvable by the Division. This step reduces the review burden on the IRB.

Completeness of IRB Submission

The Division IRB Representative checks the submission to determine if it contains the full protocol, a proposed informed consent document, any relevant grant application(s), the investigator's brochure (if one exists), any recruitment materials, including advertisements intended to be seen or heard by potential subjects, and any surveys, questionnaires or other materials to which potential subjects will be exposed (§46.111). For DHHS-supported multicenter clinical trials, the IRB should receive and review a copy of the DHHS-approved sample informed consent document and the complete DHHS-approved protocol, if they exist. The Division IRB Representative will contact the Researcher for any missing information.

Vulnerable Populations

The Division IRB Representative reviews the protocol to identify the proposed populations to be studied and to determine if protected or vulnerable populations are involved. The determination is based on the elements of 45 CFR 46

subparts B, C, and D, as well as protected populations under Utah state laws, and any other classes of human subjects that may be considered vulnerable in the context of the protocol under review.

Exempt

The Division IRB Representative determines if the proposed research qualifies as exempt under §46.101(b)[2]. The Division IRB Representative will determine if any of the *exceptions* to exempt classification are present, as defined by the Federal footnote appearing in 45 CFR § 46.101(i). Exceptions include prisoners, fetuses, pregnant women, or human in vitro fertilization, 45 CFR 46 subparts B and C. Some research with children is also excluded from the exempt category. The definition of exempt under §46.101(b) is included in Appendix A. If the research qualifies as exempt, the Division IRB Representative documents the basis for exemption under §46.101 and provides notification and documentation to the DHS IRB Chair.

Assess Risk Level

The Division IRB Representative assesses the risk level. Risk level is determined using DHS IRB definitions found in the definitions section of Appendix A and in the definitions in 45 CFR 46.

Protocol Qualifies for Expedited Review

Research proposed by a Researcher who is not a DHS employee will be considered for expedited review only if the Division has approved the research concept, will allow DHS clients, clients' family members, clients' victims, or DHS employees to be used in the study, and has approved the use of DHS employees and/or resources for the conduct of the research.

The Division IRB Representative determines and documents if the research qualifies for expedited review (found at §46.110 and 63 FR 60364-60367 at

[2]46.101(b) Unless otherwise required by Department or Agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

http://ohrp.osophs.dhhs.gov/humansubjects/guidance/expedited98.htm). For research qualifying for expedited review, the Division IRB Representative reviews the protocol in accordance with the review criteria at §46.111. Informed consent is reviewed in accordance with §46.116 (General requirements for informed consent), §46.117 (Documentation of informed consent), and DHS IRB Informed Consent Checklist. (See Appendix B.)

If the protocol requires changes before approval, the Division IRB Representative notifies the Researcher in writing of the review determination specifying the changes necessary to achieve approval. (See Appendix A for definitions of Review Determinations.) The Division IRB Representative informs the IRB Chair of the decision. The Division IRB Representative reviews all revisions and corresponds with the Researcher and IRB Chair until approval is granted. Approvable research is forwarded to the IRB Chair for processing. The Division IRB Representative may not disapprove any protocol for human subjects protections issues. (The Division IRB Representative, in his/her capacity as Division staff, may have the authority to withhold approval of, or withdraw from consideration, any research project based on Division related issues such as insufficient staff or resources, burden on staff or clients, etc.) Any protocols that the Division IRB Representative cannot approve are sent to the IRB Chair for review by the convened IRB.

Review at Convened Meeting

The Division IRB Representative serves as the Primary Reviewer for protocols from his/her Division. The Division IRB Representative presents a summary of the protocol, review criteria (§46.111) concerns, and informed consent issues (§46.116 and 46.117).

If the protocol involves prisoners (45 CFR 46 Subpart B), the prisoner representative member of the IRB must be present and contributes to the presentation. If the protocol is a biomedical protocol, the (nonvoting) physician member of the IRB must be present and contributes to the presentation. If necessary, the Researcher is invited to the meeting to provide further clarification about the protocol.

Following presentations by the primary reviewer and prisoner representative or physician, the remaining IRB members contribute to the discussion. Each IRB member is expected to review every protocol, regardless of who is the primary reviewer.

At the completion of the discussion, a motion is made, usually by the Division IRB Representative. The Chair does not make the motion. The motion includes the review determination and all required and recommended changes. If the motion is for Conditional Approval, the motion includes guidance on who may review to assure changes meeting the conditions for approval have been met.

The motion includes a determination of continuing review periods of less than one year when appropriate in studies considered high risk.

Minor changes may be reviewed and approved by the IRB Chair or designee, or the IRB Chair in consultation with the Division IRB Representative. Minor changes may include items such as addition of mandatory language to the consent form, submission of approval letters from other IRBs or institutions, spelling and grammar changes, and other clarifying changes that do not increase the risk level. Changes not considered minor require that the revised protocol be reviewed at a convened meeting.

A majority of voting members present is necessary to carry or defeat a motion.

Documentation of Initial Review Results

The IRB Chair handles all written correspondence with the Researcher. The determination letter includes the official determination (approved, conditionally approved, deferred, or disapproved), the reason for the determination and a list of all required and suggested changes. Review Determination definitions are contained in Appendix A. Sample Determination Letters are contained in Appendix C.

Approval Expiration Information for Researcher

Final approval letters contain the following language:

> "**Please note this approval will expire on [date] (one year from the date of review).** You may not conduct any research after this expiration date unless you submit an annual resubmission form that is approved by the DHS IRB. If you suspect that your research will continue beyond the expiration date you must complete the attached form along with a status report, information concerning the number of subjects enrolled, a copy of the informed consent/assent document used to enroll the most recent subject, preliminary findings, any adverse events/complaints, and resubmit for subsequent review and approval at least one month prior to expiration. If we have not received your resubmission prior to the expiration date, and if the research is ongoing, you will need to resubmit a full protocol application and request for full IRB approval. Additionally, data collected and/or analyzed during any period of time in which there was not active IRB approval will have to be destroyed or discarded.
>
> In the event that any further changes are made to the research following this approval (e.g., changes in target population, materials to which subjects are to be exposed, procedures to be employed, etc.), please document these changes on the attached and send it to the DHS IRB."

CONTINUING REVIEW

Reminder Letters

The Chair generates the continuing review (Follow-up) report monthly. The Chair sends the report to Division IRB Representatives, along with the continuing review notice template. The Division IRB Representatives send reminder letters, e-mails, and/or telephone calls to the researchers within their Division jurisdiction. All communications must be documented.

Continuing Departmental Support

The Division IRB Representatives determine if their Divisions continue to support the research. The Division IRB Representatives and IRB Chair determine if there have been noncompliance issues with the Researcher before proceeding with the review.

Distribution of Documents for Review

The Division IRB Representative provides the IRB Chair with sufficient copies of the continuing review submission based on level of review.

Expedited Review

The Division IRB Representative provides the IRB Chair with the original submission for the file.

Review at Convened Meeting

The Division IRB Representative provides the IRB Chair with the original submission for the file. The Division IRB Representative provides the IRB Chair with one copy of the entire submission, minus any pharmaceutical brochures, for each IRB member. The IRB Chair distributes a copy of each protocol and the agenda to each IRB member one week prior to each regularly scheduled meeting. The IRB Chair distributes a copy of each protocol and the agenda to each IRB member one week prior to each special meeting, whenever possible. The IRB Chair will ensure there is sufficient time to review the materials prior to a special meeting.

Expedited versus Review at Convened Meeting

The Follow-up report alerts the Division IRB Representatives that continuing review is necessary. The type of review is normally determined at the conclusion of the approval for the initial review. However, protocol changes may change the risk level. If the risk level is changed by a protocol change, the IRB Chair will

note the type of review (expedited versus full board) required for subsequent continuing review.

Expedited Review

The Division IRB Representative reviews the continuing review submission for completeness and reviews changes and any adverse event reports since the last approval date. The Division IRB Representative determines and documents if the research continues to qualify for expedited review (§46.110 and 63 FR 60364-60367 at http://ohrp.osophs.dhhs.gov/humansubjects/guidance/expedited98.htm).

The continuing review materials should include

- the number of subjects accrued;
- a summary of adverse events and any unanticipated problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review;
- a summary of any relevant literature, interim findings, and amendments or modifications to the research since the last review;
- any relevant multicenter trial reports; any other relevant information, especially information about risks associated with the research; and
- a copy of the current informed consent document and any newly proposed consent document.

If there have been changes, are proposed changes or have been any adverse event reports, the Division IRB Representative determines if the risk to subjects or others has changed.

The Division IRB Representative reviews the protocol in accordance with the review criteria at §46.111. Informed consent is reviewed in accordance with §46.116 (General requirements for informed consent), DHS IRB Checklist (Appendix B), and §46.117 (Documentation of informed consent), if appropriate.

If the protocol requires changes before approval, the Division IRB Representative notifies the Researcher in writing or by phone, fax or email of the review determination specifying the changes necessary to achieve approval. (See Review Determination definitions in Appendix A.) Division IRB Representative informs the IRB Chair of the decision. The Division IRB Representative reviews all revisions and corresponds with the Researcher and IRB Chair until approval is granted. All communication that is not in writing, will be documented via memorandum or e-mail from the Division IRB Representative to the Researcher, IRB Chair, and/or IRB file. All communication that is not in writing, will be documented via memorandum or e-mail from the Division IRB Representative to the Researcher, IRB Chair, and/or IRB file. Approvable research is forwarded to the IRB Chair for processing. The Division IRB Representative may not disapprove any protocol for human subjects protections issues. (The Division

IRB Representative, in his/her capacity as Division staff, may have the authority to withhold approval of, or withdraw from consideration, any research project based on Division-related issues such as insufficient staff or resources, burden on staff or clients, etc.) Any protocols that the Division IRB Representative cannot approve are sent to the IRB Chair for review by the convened IRB.

Review at Convened Meeting

The Division IRB Representative, as Primary Reviewer, reviews the continuing review protocol for completeness and reviews changes and any adverse event reports since the last approval date. The continuing review materials should include

- the number of subjects accrued;
- a summary of adverse events and any unanticipated problems involving risks to subjects or others and any withdrawal of subjects from the research or complaints about the research since the last IRB review;
- a summary of any relevant literature, interim findings, and amendments or modifications to the research since the last review;
- any relevant multicenter trial reports; any other relevant information, especially information about risks associated with the research; and
- a copy of the current informed consent document and any newly proposed consent document.

If there have been changes, are proposed changes or have been any adverse event reports, the Division IRB Representative determines if the risk to subjects or others has changed.

The Division IRB Representative reviews the protocol in accordance with the review criteria at §46.111. Informed consent is reviewed in accordance with §46.116 (General requirements for informed consent), DHS IRB Checklist (Appendix B), and §46.117 (Documentation of informed consent), if appropriate.

The Division IRB Representative presents the protocol to the convened meeting. If the protocol involves prisoners (45 CFR 46 Subpart B), the prisoner representative member of the IRB must be present and contributes to the presentation. If the protocol is a biomedical protocol, the (nonvoting) physician member of the IRB must be present and contributes to the presentation. If necessary, the Researcher is invited to the meeting to provide further clarification about the protocol.

Following presentations by the primary reviewer and prisoner representative or physician, the remaining IRB members contribute to the discussion. Each IRB member is expected to review every protocol, regardless of who is the primary reviewer.

At the completion of the discussion, a motion is made, usually by the Division IRB Representative. The Chair does not make the motion. The motion includes the review determination and all required and recommended changes. If the motion is for Conditional Approval, the motion includes guidance on who may review to assure changes meeting the conditions for approval have been met. The motion includes a determination of continuing review periods of less than one year when appropriate in studies considered high risk.

Minor changes may be reviewed and approved by the IRB Chair or designee, or the IRB Chair in consultation with the Division IRB Representative. Minor changes may include items such as addition of mandatory language to the consent form, submission of approval letters from other IRBs or institutions, spelling and grammar changes, and other clarifying changes that do not increase the risk level. Changes not considered minor require that the revised protocol be reviewed at a convened meeting.

A majority of members present is necessary to carry or defeat a motion.

Documentation of Continuing Review Results

The IRB Chair handles all written correspondence with the Researcher. The determination letter includes the official determination (approved, conditionally approved, deferred, or disapproved), the reason for the determination and a list of all required and suggested changes. Review Determination definitions are contained in Appendix A, and sample Determination Letters are contained in Appendix C.

Approval Expiration Information for Researcher

Final approval letters contain the following language:

> "**Please note this approval will expire on [date] (one year from the date of review).** You may not conduct any research after this expiration date unless you submit an annual resubmission form that is approved by the DHS IRB. If you suspect that your research will continue beyond the expiration date you must complete the attached form along with a status report, information concerning the number of subjects enrolled, a copy of the informed consent/assent document used to enroll the most recent subject, preliminary findings, any adverse events/complaints, and resubmit for subsequent review and approval at least one month prior to expiration. If we have not received your resubmission prior to the expiration date, and if the research is ongoing, you will need to resubmit a full protocol application and request for full IRB approval. Additionally, data collected and/or analyzed during any period of time in which there was not active IRB approval will have to be destroyed or discarded.

In the event that any further changes are made to the research following this approval (e.g., changes in target population, materials to which subjects are to be exposed, procedures to be employed, etc.), please document these changes on the attached and send it to the DHS IRB."

APPEALS PROCESS

If the DHS IRB decides to disapprove a research activity, it shall include in its written notification to the Researcher, a statement of the reasons for its decision and give the Researcher an opportunity to respond in writing and in person. The Researcher may appeal the decision to the DHS Director or Deputy Director.

While DHS IRB approved research may be subject to further appropriate review and approval or disapproval by the DHS Director or Deputy Director, the DHS Director or Deputy Director may not approve federally-funded research if it has not been approved by the IRB (45 CFR 46.112). The Director and/or Deputy Director may appoint an appeals board composed of both medical and non-medical IRB representatives and appropriate representatives from the DHS executive staff to make a recommendation to him/her regarding an appeal. If the DHS Director or Deputy Director receives a recommendation from the appeals board that does not correspond with the original IRB determination, the DHS Director or Deputy Director may request the IRB to re-review the protocol. The Researcher will be notified of the request for re-review and shall submit any additional information needed by the DHS IRB to complete a re-review. If the study is covered by federal regulations, the DHS Director or Deputy cannot reverse a decision to disapprove a study made by the appeals board.

INFORMED CONSENT DOCUMENTS

Approval and Expiration Dates

The Office for Human Research Protections (OHRP) recommends that IRBs affix the approval and expiration dates to all approved informed consent documents and stipulate that copies of these dated documents must be used in obtaining consent. This procedure helps ensure that only the current, IRB-approved informed consent documents are presented to subjects and serves as a reminder to the investigators of the need for continuing review. The DHS IRB often reviews protocols that have been reviewed and approved by other IRBs. Requiring separate dates corresponding to the DHS IRB dates has been shown to be problematic. Therefore, for protocols which have been reviewed and approved by another IRB, such as the University of Utah IRB, the DHS IRB will not require separate approval and expiration dates be affixed to the document, but will accept the dates affixed by the other IRB. However, protocols from Valley Mental Health (VMH) must have the DHS IRB approval and expiration dates affixed.

MANDATORY REPORTING LANGUAGE

Utah statute requires everyone to report actual or suspected abuse, neglect, or exploitation of a child or disabled, elderly or vulnerable adult. In order to protect potential research subjects' right to be informed of all foreseeable risks related to participating in a research study, the DHS IRB requires that all informed consent or permission forms include language informing the signatory of the mandatory reporting requirements.

DHS requires disclosure language in every consent form for the protection of potential human research subjects. The language, which reflects the requirement of *Utah Code Annotated* §§ 62A-3-301, 305, 306 and 76-5-111, is as follows:

> Utah law requires us to report any suspected or actual abuse, neglect, or exploitation of a child, an adult 65 or older, or an adult who has a mental or physical impairment, which affects that person's ability to provide for or protect him/herself. If the researcher has reason to believe that such abuse, neglect, or exploitation has occurred, the researcher will report this to Child Protective Services (CPS), Adult Protective Services (APS), or the nearest law enforcement agency.

The mandatory reporting language will be included verbatim whenever possible, or will be included in language understandable to the signatory including the spirit of the required statement. For informed assent documents, the language may be simplified so that a child can understand the reporting requirements.

REVIEW OF PLACEBO STUDIES.

In addition to the requirements set forth in federal law and regulation, and elsewhere in Department of Human Services (DHS) policy, research protocols that involve the use of a pharmaceutical or medical placebo, must meet the conditions outlined below, in order to assure the safety of human subjects. The DHS IRB will apply the following criteria in reviewing placebo studies proposing to recruit individuals as research participants who receive services that are either partially or fully funded by monies allocated through the Department of Human Services (DHS):

1. The following individuals are prohibited from inclusion in any placebo studies: an individual having any pending legal or criminal charge or action, or who has pending or a reasonable potential for court involvement, or a person who is incarcerated or is in detention, or who is pending or having completed a competency evaluation or commitment procedure. However, if the individual has entered the study prior to

involvement with the legal system, the courts, or the beginning of civil or criminal legal proceedings, and subsequently becomes involved in any such action, a referral will then be made to the agency or entity that has assumed guardianship or responsibility for that person, if any, and to the appropriate court to determine whether continued participation in the study is appropriate.

2. No minor who is under the guardianship or custody of the Department of Human Services (DHS), the Division of Child and Family Services (DCFS), the Division of Substance Abuse and Mental Health (DSAMH), the Division of Youth Corrections (DYC), or the Division of Services for People with Disabilities (DSPD) may be recruited, enrolled, or participate in any research study that involves the use of a placebo. If a child has previously entered a study involving placebos prior to entrance into state guardianship or custody, then a referral will be made to the DHS agency or entity that has guardianship or custody, to determine whether the child's continued participation in the study is appropriate. That determination shall be consistent with existing DHS policy, and state and federal law, taking into consideration the opinions of medical and psychological experts who have provided care for the child prior to and during the study. In addition, the child's Guardian ad Litem (GAL), if one has been appointed, shall be notified by telephone, as well as by certified mail, and a copy of that letter shall be kept with the child's DHS records, and be sent to the DHS IRB. In every case, it must be determined that the biological or custodial parent(s), prior to the child's entrance into state custody or guardianship, had agreed to and signed an informed consent to the study prior to the child's participation in the study.

3. The research participant (human subject) must give written informed consent, and shall have been determined to be competent to grant that consent. Where children or disabled adults are involved as human subjects, adequate provisions must be made for obtaining the assent of the children or disabled adults, in addition to permission via written informed consent of their parents, guardians or legally authorized representatives, in accordance with federal law. (See, 45 CFR § 46.408.)

4. If a proven or known effective standard of care or treatment exists (whether or not the standard of care has been subjected to empirical testing), that treatment shall not be withheld, and placebos shall not be used. Placebos may only be used in studies where no proven or known effective standard of care, prophylactic, diagnostic or therapeutic method exists.

5. Recruitment for the study shall not be limited exclusively to subjects who are receiving services that are either partially or fully funded by monies allocated through the Department of Human Services (DHS).

6. Remuneration for participation in the study must not be coercive, or have the appearance or effect of being coercive; or, be offered to entice individuals to participate in the study rather than receive traditional treatment. Compensation to research participants who are enrolled in placebo studies must be restricted to fair and reasonable remuneration. Only the Institutional Review Board (IRB) at a convened meeting, with a quorum of its members present, may assess and determine a compensation that is fair and equitable.

7. If the child or adult has a current DSM-IV diagnosis of major mental illness at the beginning of a proposed study, the individual will be excluded from participation in placebo studies. Major mental illness will be defined as Major Depression, Manic Depression, Schizophrenia, Disassociative Disorder, other psychotic illnesses, Attention-Deficit Hyperactivity Disorder, Post Traumatic Stress Disorder, Borderline Personality Disorder, Reactive Attachment Disorder, and Panic Disorder.

8. Frequent and close clinical monitoring (as dictated by the medical need of each client) is required in order to assure the ongoing safety and well-being of each human subject. That monitoring shall be documented by the research/medical personnel in each client's clinical record.

9. Any individual with homicidal or suicidal ideations, or who poses a clear threat to themselves or others, is prohibited from participation in any study that involves the use of a placebo.

REVIEW OF PROTOCOL CHANGES

Distribution of Documents for Review

The Division IRB Representative provides the IRB Chair with sufficient copies of the protocol change request submission based on level of review.

Expedited Review

The Division IRB Representative provides the IRB Chair with the original submission for the file.

Review at Convened Meeting

The Division IRB Representative provides the IRB Chair with the original submission for the file. The Division IRB Representative provides the IRB Chair with one copy of the entire submission, minus any pharmaceutical brochures, for each IRB member. The IRB Chair distributes a copy of each protocol and the agenda to each IRB member one week prior to each regularly scheduled

meeting. The IRB Chair distributes a copy of each protocol and the agenda to each IRB member one week prior to each special meeting, whenever possible. The IRB Chair will ensure there is sufficient time to review the materials prior to a special meeting.

Review of Proposed Protocol Changes

Expedited Review of Minor Changes

The Division IRB Representative may review minor changes in previously approved research, which can be approved under an expedited review procedure in accordance with §46.110(b)(2). Minor changes include any changes, which do not increase the risks to subjects or others. Examples include change of contact information, spelling and grammatical changes, minor changes to recruitment materials, etc.

Review of Proposed Protocol Changes at Convened Meetings

In accordance with §46.108(b), review of proposed protocol changes must be conducted by the IRB at convened meetings at which a majority of the members of the IRB are present, including at least one member whose primary concerns are in nonscientific areas, except where expedited review is appropriate under §46.110(b)(2).

Protocol Revisions

Before final approval of protocol changes, each revision to a research protocol will be incorporated into the written protocol. This practice ensures that there is only one complete protocol with the revision dates noted on each revised page and the first page of the protocol itself. This procedure is consistent with the procedure used for revised and approved informed consent documents, which then supersede the previous one.

REVIEW OF ADVERSE EVENTS (AE) OR SERIOUS ADVERSE EVENTS (SAE)

Distribution of Documents for Review

Expedited Review

The IRB Chair provides the Division IRB Representative with a copy of the event report for review.

Review at Convened Meeting

The IRB Chair provides each IRB member and the nonvoting physician member with one copy of the event report for review. The IRB Chair distributes the event report to each IRB member and the nonvoting physician member with the meeting packet one week prior to each regularly scheduled meeting. The IRB Chair distributes a copy of the event report to each IRB member and the nonvoting physician member one week prior to each special meeting, whenever possible. The IRB Chair will ensure there is sufficient time to review the materials prior to a special meeting. If prisoners are involved, the IRB Chair will ensure the prisoner representative has sufficient time to review the report and will attend the convened meeting.

Possible Results of Review

The nonvoting physician member will review the AE or SAE and make recommendations for resolution (if necessary) to the DHS IRB Chair. If the nonvoting physician recommendations indicate concerns with the research protocol, study procedure, or an increase in risk to study participants, the DHS IRB members will review the SAE at a convened meeting with the nonvoting physician member present. Following review at a convened meeting, the DHS IRB has a choice for the review determination depending on an increase in risk, the severity of the event, the location of the event (other clinical population versus DHS client population), frequency of event, reason for event, etc. The options available to the IRB include record the event and file it, discuss event further with the Researcher for more information, require protocol or consent form changes, require the Researcher to reconsent current subjects, suspend study or new enrollment pending further review or changes, or terminate study. The determination will be made on a case-by-case basis.

REPORTING FINDINGS AND ACTIONS TO RESEARCHERS AND THE INSTITUTION

Reporting Initial Review Findings and Actions to the Researcher

During the initial review of a protocol, the Division IRB Representative may correspond in writing or by phone, fax or email with the Researcher requesting missing, additional or clarifying information. All communication that is not in writing, will be documented via memorandum or e-mail from the Division IRB Representative to the Researcher, IRB Chair, and/or IRB file.

Following initial expedited review of a protocol that has received an approval or conditional approval determination from the Division IRB Representative, the IRB Chair prepares an approval letter for signature for the Deputy Director of DHS. If the protocol is deferred because of lack of information, the IRB Chair prepares and signs a deferral letter. The Division IRB Representative may not disapprove any protocol for human subjects protections issues. (The Division IRB Representative, in his/her capacity as Division staff, may have the authority to

withhold approval of, or withdraw from consideration, any research project based on Division related issues such as insufficient staff or resources, burden on staff or clients, etc.)

Following initial review at a convened meeting of a protocol that has received an approval or conditional approval determination from the IRB, the IRB Chair prepares an approval or conditional approval letter for signature for the Deputy Director of DHS. If the protocol is deferred because of lack of information, the IRB Chair prepares and signs a deferral letter. A letter informing the Researcher of disapproval at a convened meeting is prepared by the IRB Chair for signature for the DHS Deputy Director.

Reporting Continuing Review Findings and Actions to the Researcher

Following continuing expedited review of a protocol that has received an approval or conditional approval determination from the Division IRB Representative, the IRB Chair prepares an approval or conditional approval letter, which may be under the signature of the DHS IRB Chair or the DHS Deputy Director. If the approval or conditional letter is from the DHS IRB Chair, the Deputy Director will receive a courtesy copy of the correspondence. If the protocol is deferred because of lack of information, the IRB Chair prepares and signs a deferral letter. The Division IRB Representative may not disapprove any protocol for human subjects protections issues. (The Division IRB Representative, in his/her capacity as Division staff, may have the authority to withhold approval of, or withdraw from consideration, any research project based on Division related issues such as insufficient staff or resources, burden on staff or clients, etc.)

Following continuing review at a convened meeting of a protocol that has received an approval or conditional approval determination from the IRB, the IRB Chair prepares an approval or conditional approval letter for signature for the Deputy Director of DHS. If the protocol is deferred because of lack of information, the IRB Chair prepares and signs a deferral letter. A letter informing the Researcher of disapproval at a convened meeting is prepared by the IRB Chair for signature for the Deputy Director of DHS.

Reporting Initial Review Findings and Actions to the Institution

Preparing review findings and actions letters for the signature of the Deputy Director ensures the institution is informed of all IRB actions. Division IRB Representatives are expected to inform their respective Divisions of all IRB decisions.

Reporting Initial Review Findings and Actions to the IRB

All approvals from exempt and expedited reviews for the previous month are listed in the agenda and minutes of the monthly meeting to ensure all members are informed of actions taken between meetings. Final minutes are distributed to all IRB members each month.

DETERMINING WHICH PROJECTS REQUIRE REVIEW MORE OFTEN THAN ANNUALLY

Most DHS IRB reviews involve behavioral research protocols of minimal or less than minimal risk. For the protocols involving greater than minimal risk, the IRB assesses the need for continuing review on a more frequent than annual review schedule on a case-by-case basis. This determination is based on the type of and level of risk involved, adverse event reports related to the project or similar projects, reputation of Researcher regarding past noncompliance or research misconduct findings by DHS, etc. The DHS does not allow any DHS clients to be involved in Phase I or Phase II clinical trials.

DETERMINING WHICH PROJECTS REQUIRE VERIFICATION FROM SOURCES OTHER THAN THE INVESTIGATORS THAT NO MATERIAL CHANGES HAVE OCCURRED SINCE PREVIOUS IRB REVIEW

The IRB assesses the need for verification that no material changes have occurred since previous review on a case by case basis. This determination is based on the type of and level of risk involved, adverse event reports related to the project or similar projects, reputation of Researcher regarding past noncompliance or research misconduct findings by DHS, etc. For example, the IRB has witnessed the informed consent process for some protocols on an as needed basis. The formal monitoring has followed adverse event reporting.

ENSURING PROMPT REPORTING OF PROPOSED CHANGES IN APPROVED RESEARCH

Each Researcher signs a “Research Agreement” pledging to notify the DHS IRB immediately of any proposed changes in the research procedures or methods, and not to implement those changes unless the IRB approves them. In addition, all approval letters contain the following language:

> **Please note this approval will expire on [date] (one year from the date of review).** You may not conduct any research after this expiration date unless you submit an annual resubmission form that is approved by the DHS IRB. If you suspect that your research will continue beyond the expiration date you must complete the attached form along with a status report, information concerning the number of subjects enrolled, a copy of

the informed consent/assent document used to enroll the most recent subject, preliminary findings, any adverse events/complaints, and resubmit for subsequent review and approval at least one month prior to expiration. If we have not received your resubmission prior to the expiration date, and if the research is ongoing, you will need to resubmit a full protocol application and request for full IRB approval. Additionally, data collected and/or analyzed during any period of time in which there was not active IRB approval will have to be destroyed or discarded.

In the event that any further changes are made to the research following this approval (e.g., changes in target population, materials to which subjects are to be exposed, procedures to be employed, etc.), please document these changes on the attached and send it to the DHS IRB.

ENSURING PROMPT REPORTING OF UNANTICIPATED PROBLEMS RESULTING IN RISKS TO SUBJECTS OR OTHERS

All reports of unanticipated adverse events must be reported to the IRB within 10 working days from the knowledge of, or notice of, the event. Failure to report serious unanticipated adverse events involving DHS clients may result in loss of access to DHS clients for the current project and for future projects. Each Researcher signs a “Research Agreement” pledging to report any significant adverse reactions experienced by the subjects as a result of enrollment in the study.

ENSURING COMPLIANCE WITH 45 CFR 46 OR THE REQUIREMENTS OF THE IRB

Each Researcher signs a “Research Agreement” pledging to comply with 45 CFR 46 and the requirements of the DHS IRB. Researcher’s noncompliance with 45 CFR 46 or the requirements of the DHS IRB may result in loss of access to DHS clients for the current project and for future projects.

ENSURING PROMPT REPORTING OF ANY SUSPENSION OR TERMINATION OF IRB APPROVAL

Suspension Resulting from Expiration of Approval

Suspension of IRB approval resulting from expiration of approval will be reported promptly by the IRB Chair to the IRB members, the Deputy Director of DHS, and the grants office, if applicable. Division IRB Representatives will advise their Divisions of the suspension. For research involving other institutions, such as the University of Utah, the IRB Chair will notify those institutions of the suspension.

Other Suspensions

Suspension of IRB approval resulting from reasons other than expiration of approval (such as concerns arising from adverse events, over enrollment, complaints, or allegations of noncompliance or research misconduct) will be reported promptly by the IRB Chair to the Researcher, the Deputy Director of DHS, the IRB members, OHRP and the federal Department or Agency head, and the grants office, if applicable. Division IRB Representatives will advise their Divisions of the suspension. For research involving other institutions, such as the University of Utah, the IRB Chair will notify those institutions of the suspension. The IRB Chair will provide an explanation of the suspension. Results of any investigations will be shared with the IRB members, the Deputy Director and OHRP.

Termination of IRB Approval

The IRB has the authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any termination of approval will include a statement of the reasons for the IRB's action and will be reported promptly by the IRB Chair to the Researcher, the Deputy Director of DHS, the IRB members, OHRP and the federal Department or Agency head, and the grants office, if applicable. (§46.113) Division IRB Representatives will advise their Divisions of the suspension. For research involving other institutions, such as the University of Utah, the IRB Chair will notify those institutions of the termination.

RETENTION OF IRB RECORDS

IRB administrative records will be retained for at least 3 years, and IRB records relating to research that is conducted will be retained for at least 3 years after completion of the research. All records will be stored with the IRB Chair and will be accessible for inspection and copying by authorized representatives of the US Department of Health and Human Services (DHHS) at reasonable times and in a reasonable manner (§46.115(b)).

CHILDREN IN DCFS OR DYC CUSTODY

In addition to routine IRB procedures, when a Researcher proposes a research study involving children in Division of Child and Family Services (DCFS) or Division of Youth Corrections (DYC) custody or guardianship, the Researcher and the DCFS or DYC IRB Representative must follow internal DCFS or DYC procedures for granting consent for the children to be involved in the research project. For a copy of DCFS or DYC procedure concerning research with children in custody contact the DCFS or DYC IRB representative.

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 (HIPAA)

HIPAA, or “the Privacy Act”, effective April 14, 2003, was designed to protect medical records privacy. Although HIPAA was not written with research in mind, 45 CFR 164.501, 164.508, and 164.512(i) address HIPAA privacy in research. Also, many institutions nationally have added HIPAA compliance to the duties of the IRB. The DHS IRB will define specific HIPAA/IRB review related procedures prior to the implementation of HIPAA. The DHS IRB will provide guidance to DHS researchers regarding HIPAA requirements in research studies. (For more information, see http://www.hhs.gov/ocr/hipaa/privacy.html

APPENDIX A

DEFINITIONS AND REFERENCES

DHS IRB DEFINITIONS

Review Determinations

- ***Approved.*** Protocol accepted without change.
- ***Conditional approval.*** IRB requires specific revisions or verifications necessary in order to receive "approval" or "final approval" (See conditional approval letter)
- ***Deferred.*** IRB did not have sufficient information to complete a review. The convened IRB requests substantive clarifications or modifications regarding the protocol or informed consent documents that are directly relevant to the determinations required by the IRB under §46.111. In those cases, the IRB Chair sends a letter to the Researcher requesting additional information, modifications or clarifications in order for the DHS IRB to complete its review.
- ***Disapproved.*** The IRB could not approve the protocol, with or without changes. The risk to human subjects outweighs any benefit to the subjects. If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing.

REGULATORY DEFINITIONS (45 CFR 46)

Debriefing means giving subjects previously undisclosed information about the research project following completion of their participation in research. (Note that this usage, which occurs within the behavioral sciences, departs from Standard English, in which debriefing is obtaining rather than imparting information.)

Department or ***Agency head*** means the head of any Federal Department or Agency and any other officer or employee of any Department or Agency to whom authority has been delegated.

Exempt is defined by §46.101(b):

(b) Unless otherwise required by Department or Agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy:[1]

(1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as (i) research on

regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and

(ii) any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

(3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if:

(i) the human subjects are elected or appointed public officials or candidates for public office; or

(ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

(4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

(5) Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs;
(ii) procedures for obtaining benefits or services under those programs;
(iii) possible changes in or alternatives to those programs or procedures; or
(iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Taste and food quality evaluation and consumer acceptance studies,

(i) if wholesome foods without additives are consumed or
(ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Paragraph (b) above contains an important footnote regarding situations under which an exemption may not be granted. The footnote states:

[1] Institutions with DHHS-approved assurances on file will abide by provisions of Title 45 CFR Part 46 Subparts A-D. Some of the other departments and agencies have incorporated all provisions of Title 45 CFR Part 46 into their policies and procedures as well. However, the exemptions at 45 CFR 46.101(b) do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization, Subparts B and C. The exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures or observation of public behavior, does not apply to research with children, Subpart D, except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed.

Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains

- data through intervention or interaction with the individual, or
- identifiable private information.

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject. (For example, an interaction might include collection of data from the subject through administration of surveys or questionnaires.)

Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the

information) in order for obtaining the information to constitute research involving human subjects.

Institution means any public or private entity or Agency (including Federal, State, and other agencies).

Institutional Review Board (IRB) approval means the determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and Federal requirements.

Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

Medical device means a diagnostic or therapeutic article that does not achieve any of its principal intended purposes through chemical action within or on the body. Such devices include diagnostic test kits, crutches, electrodes, pacemakers, arterial grafts, intraocular lenses, and orthopedic pins or other orthopedic equipment.

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities, which meet this definition, constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities.

Research subject to regulation, and similar terms are intended to encompass those research activities for which a Federal Department or Agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a Federal Department or Agency solely as part of the Department's or Agency's broader responsibility to regulate certain types of activities whether research or non-research in nature (for example, Wage and Hour requirements administered by the Department of Labor).

INFORMED CONSENT CHECKLIST

The DHS IRB uses an Informed Consent Checklist **(See Appendix B)** when reviewing the informed consent procedures and forms for each protocol. The DHS IRB has a checklist which incorporates the requirements under §46.116 and includes additional requirements unique to DHS and/or the State of Utah. This checklist is based on the requirements under §46.116, but contains additional requirements that are unique to the DHS and/or the State of Utah **(See Appendix B)**. The federal requirements are listed below.

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of § 46.116, in seeking informed consent the following information shall be provided to each subject:

(1) a statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
(2) a description of any reasonably foreseeable risks or discomforts to the subject;
(3) a description of any benefits to the subject or to others which may reasonably be expected from the research;
(4) a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
(5) a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
(6) for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
(7) an explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
(8) a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

(b) additional elements of informed consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

(1) a statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
(2) anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
(3) any additional costs to the subject that may result from participation in the research;
(4) the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
(6) the approximate number of subjects involved in the study.

APPENDIX B

DHS INFORMED CONSENT CHECKLIST

Where informed consent is required, the Researcher shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative. If the subject is a child or an adult with a legally authorized representative or guardian, but the subject is nevertheless capable of consenting to the research project, the Researcher must also obtain the informed assent of that child or adult. (As used in the following provisions of this policy, the term "subject" includes both the subject and the subject's legally authorized representative, if any.)

The Researcher shall give each subject a written informed-consent form that explains the study in simple, easily-understood language and easy-to-read type. The Researcher shall give each subject a reasonable opportunity to read the form and ask questions before signing the form.

At a minimum, the informed-consent form shall comply with the following requirements:

A. The informed-consent form shall not include any exculpatory language that requires or appears to require the subject to waive any of the subject's legal rights, nor may the form release or appear to release the Researcher, investigator, sponsor, the institution or their agents from liability for negligent or intentional harm.

B. The Researcher shall provide the subject with sufficient information and opportunity to consider whether or not to participate in the study.

C. The Researcher shall ensure that the possibility of coercion or undue influence is minimized.

D. The Researcher shall give the subject a written statement that clearly explains the following:
   1. That the study involves research
   2. The purposes of the research
   3. How long the subject's participation will last
   4. The procedures that the Researcher will use
   5. Whether any of procedures the Researcher plans to use are experimental, and if so, which ones
   6. The approximate number of subjects who will be involved in the study.
   7. That participation in the research study is voluntary, and that refusal to participate in the study will not result in any penalty or loss of benefits to which the subject is otherwise entitled; and
   8. That the subject may withdraw from the study at any time without penalty and without loss of any benefits to which the subject is otherwise entitled.

E. The Researcher shall give the subject a written description of any reasonably foreseeable risks, discomforts or consequences that the subject might experience as a result of participating in the study.

F. For research involving more than minimum risk, the Researcher shall give the subject a written explanation of:

1. Whether the subject may obtain compensation for any injuries or damages arising out of such risk;
2. Whether any medical treatment is available for such injuries or damages, and if so, what those treatments are and whether the Researcher will provided them free of charge to the subject; and
3. Whom the subject should contact to obtain further information about the risk of injury or damage or about compensation or treatment.

G. The Researcher shall give the subject a written description of any additional costs that the subject may incur as the result of participating in the research study.

H. The Researcher shall give the subject a written description of any benefits that the research project will provide to the subject or others.

I. The Researcher shall give the subject a written disclosure of any appropriate alternative procedures or courses of treatment that might be advantageous to the subject.

J. If any of the Researcher's treatments or procedures poses currently unforeseeable risks to the subject or to an embryo or fetus if the subject becomes pregnant, the Researcher shall notify the subject in writing about this risk. (The Department will not approve any studies that involve foreseeable risk to a pregnant subject or to the subject's embryo or fetus.)

K. The Researcher shall give the subject a written statement describing the extent to which the Researcher will maintain confidentiality of records.

L. The Researcher shall notify the subject in writing whom the subject should contact if the subject has questions about the research or the subject's rights, including the DHS IRB contact.

M. The Researcher shall give the subject a written statement listing the anticipated circumstances in which the Researcher may terminate the subject's participation in the research study.

N. The Researcher shall give the subject a written description of the consequences of a subject's decision to withdraw from the research study, and a description of the procedures for orderly termination of the subject's participation in the study.

O. The Researcher shall give the subject a written statement indicating that if the Researcher makes significant new research findings, which relate to the subject's willingness to continue participation in the research project, the Researcher will notify the subject about those findings during the study.

P. The Researcher shall give the subject a written statement indicating that if the subject discloses any actual or suspected abuse, neglect or exploitation of a child, disabled adult or elder adult, the Researcher must report this abuse to the authorities, as required by federal and state laws.

Q. If the subject is a child and the State has guardianship over the child, the Researcher shall give the subject a written statement indicating that the child is represented by the Office

of the Guardian Ad Litem. To facilitate access to the Guardian Ad Litem, the statement shall also include the Guardian Ad Litem's phone number: (801) 578-3962.

R. The informed consent must disclose if the research is being conducted to fulfill the requirements for a master's thesis or doctoral dissertation.

APPENDIX C

TEMPLATES

FINAL APPROVAL LETTER – EXAMPLE 1

(WRITTEN AFTER CONDITIONS/CHANGES HAVE BEEN RESOLVED)

May 11, 2000

RESEARCHER
ADDRESS

Subject: Title of Research Proposal, # 000117, Final Approval

Dear Ms. Researcher's Name:

We appreciate receipt of the requested modifications to the Informed Consent/Assent form. The full subject protocol has been reviewed by _(IF NEEDS MED REVIEW BY MEDICAL/PSYCHIATRIC CONSULTANT__; and the Department of Human Services' Institutional Review Board (DHS IRB). Based on their review and recommendations, I am pleased to notify you that I have approved the subject research proposal and the revised Informed Consent/Assent form submitted on December 21, 1999. Attached is a copy of the approved Informed Consent/Assent form. ***Please note this approval will expire on [date] (one year from the date of review).*** *You may not conduct any research after this expiration date unless you submit an annual resubmission form that is approved by the DHS IRB. If you suspect that your research will continue beyond the expiration date you must complete the attached form along with a status report, information concerning the number of subjects enrolled, a copy of the informed consent/assent document used to enroll the most recent subject, preliminary findings, any adverse events/complaints, and resubmit for subsequent review and approval at least one month prior to expiration. If we have not received your resubmission prior to the expiration date, and if the research is ongoing, you will need to resubmit a full protocol application and request for full IRB approval. Additionally, data collected and/or analyzed during any period of time in which there was not active IRB approval will have to be destroyed or discarded.*

In the event that any further changes are made to the research following this approval (e.g., changes in target population, materials to which subjects are to be exposed, procedures to be employed, etc.), please document these changes on the attached and send it to the DHS IRB.

If you need further assistance, please contact Mary Caputo at 538-4295. Once your research is completed, please send a copy of your final report to the DHS IRB to allow its members and the Department to benefit from your research findings.

Sincerely,

Mark E. Ward, Deputy Director
Department of Human Services

Attachment

cc: DIV IRB REP, AGENCY
Mary Caputo, DHS IRB

FINAL APPROVAL LETTER – EXAMPLE 2
(WRITTEN AFTER CONDITIONS/CHANGES HAVE BEEN RESOLVED)

July 17, 2000

Ms. Researcher
Address

Subject: Study Title, # 000xxx, Final Approval

Dear Ms. Researcher:

Based on the review and recommendations of the Department of Human Services Institutional Review Board (DHS IRB), and receipt of documentation of IRB approval from the University of Utah, I am pleased to notify you that I have approved the subject research proposal. ***Please note this approval will expire on [date] (one year from the date of review).*** *You may not conduct any research after this expiration date unless you submit an annual resubmission form that is approved by the DHS Institutional Review Board (IRB) or one of its representatives. If you suspect that your research will continue beyond the expiration date you must complete the attached form along with a status report, information concerning the number of subjects enrolled, a copy of the informed consent/assent document used to enroll the most recent subject, preliminary findings, any adverse events/complaints, and resubmit for subsequent review and approval at least one month prior to expiration. If we have not received your resubmission prior to the expiration date, and if the research is ongoing, you will need to resubmit a full protocol application and request for full IRB approval. Additionally, data collected and/or analyzed during any period of time in which there was not active IRB approval will have to be destroyed or discarded.*

In the event that any further changes are made to the research following this approval (e.g., changes in target population, materials to which subjects are to be exposed, procedures to be employed, etc.), please document these changes on the attached and send it to the DHS IRB.

If you need further assistance, please contact Mary Caputo at 538-4295. Once your research is completed, please send a copy of your final report to the DHS IRB to allow its members and the Department to benefit from your research findings.

Sincerely,

Mark E. Ward, Deputy Director
Department of Human Services

Attachment

cc: DHS IRB REP. AGENCY
Mary Caputo, DHS IRB

Change, Ongoing, or Annual Resubmission of Research Proposal

UTAH DEPARTMENT OF HUMAN SERVICES

Institutional Review Board (IRB), Mary Caputo, Chairperson (801-538-4295)
120 North 200 West, Room 221, Salt Lake City, Utah 84103

Date of Submission:_____ DHS IRB #:_____
Researcher's Name:_____
Street Address:_____ E-mail: _____
Work Phone:_____ Home Phone:_____ FAX:_____
Start Date: _____ Anticipated End Date: _____

NOTE: *All research projects must be reviewed by the Department's IRB no less than annually. If the Researcher plans to make* ***any*** *changes to the research design, instruments, or surveys, the Researcher must submit those changes for review, and obtain approval* ***before*** *the changes are implemented.*

1. **TITLE:_____**
2. **NATURE OF STUDY:**

3. **STUDY STATUS:** *(Check one)*

_____ **NO CHANGES** have been made to the study protocol or instruments since the DHS IRB last approved the study. ***Please provide an update of the study status including number of subjects accrued, complaints/adverse events, preliminary findings, a copy of consent document used for most recent subject enrollment (see #4 below).***

_____ **CHANGES ARE PROPOSED** for the study protocol and instruments since the DHS IRB last approved the study. ***Please attach a list that itemizes each change proposed for the protocol or instruments. Attach copies of all proposed protocol changes and all new or modified survey instruments or questionnaires. Include an update of the study status as requested #3 below.***

_____ **STUDY COMPLETED.** ***Please attach a copy of the final report.***

4. **UPDATE OF STUDY STATUS:** (*Please attach additional pages as necessary*)

5. **REQUIRED SIGNATURE:**

Principal Investigator:_____

CLOSURE LETTER
(WRITTEN AFTER ATTEMPTS AT TELEPHONE AND/OR WRITTEN CONTACT HAVE FAILED)

July 26, 2000

PI Name and Degree/Title
University of _____, College of _____
Address
City, STATE Zip

Subject: Research Project Title, # 999999, Expired Protocol

Dear Dr. _____:

Mr./Ms./Dr. _____ of the Department of Human Services (DHS), Division of _____, has attempted on several occasions to contact you at the College of _____ and has left several messages requesting a return call. I have also attempted to contact you by telephone today and left you a message. The purpose of his/her telephone contact was to advise that the DHS Institutional Review Board's (DHS IRB) approval of the subject research protocol was at risk of expiring. The approval did in fact expire on _____. As you are aware, no work may take place on studies without an active IRB approval. Because your approval has expired, and you have failed to respond to our requests for information regarding the status of your research, we are closing our records on this protocol.

Please complete the attached Data Exclusion Verification form and return to us as soon as possible. Please be advised that because you have not returned our calls, our ability to comply with federal reporting and review requirements has been compromised. As a representative of the College of _____, you have also compromised our ability to approve future research proposals from you and/or the College of _____. If you have information concerning the disposition of the subject protocol, please call me at 538-4295.

Sincerely,

Division Representative or Chair
DHS Institutional Review Board

cc: College Dean, Name of University
Mark E. Ward, EDO
DHS Division IRB Representative or IRB Chair (depending on who sends)

CONDITIONAL APPROVAL – EXAMPLE 1

May 11, 2000

RESEARCHER
ADDRESS

Subject: Title of Research Proposal, # 000117, Conditional Approval Pending U of U IRB Approval

Dear Ms. Researcher's Name:

The Department of Human Services' (DHS) Institutional Review Board (DHS IRB) has received and reviewed the research proposal titled Title of Proposed Research. Based on the IRB members' recommendation, I am pleased to notify you that I have *conditionally approved* the subject research proposal pending receipt of verification that the University of Utah's Institutional Review Board (IRB) has approved the subject research. This conditional approval will allow you to proceed with your research, but ***does not allow you to contact or involve human subjects***.

Please provide the above-requested verification to Mary Caputo, DHS IRB Chair, at 120 North 200 West, Room 221, Salt Lake City, Utah 84103. Upon receipt of such verification, we will issue a letter with our final approval decision which will allow you to fully implement your research.

If you need further assistance, please call Ms. Caputo at 538-4295.

Sincerely,

Mark E. Ward, Deputy Director
Department of Human Services

cc: Division IRB Rep, Agency
Mary Caputo, DHS IRB

CONDITIONAL APPROVAL – EXAMPLE 2

January 11, 2002

Researcher
Address

Subject: Title, DHS IRB # 010181, **Conditional Approval**

Dear Dr. Researcher:

The Department of Human Services' (DHS) Institutional Review Board (DHS IRB) has received and reviewed the research proposal titled Title. Based on the IRB members' recommendation, I am pleased to notify you that I have ***conditionally*** *approved* the subject research proposal. This conditional approval will allow you to proceed with your research plan, but ***does not allow you to contact or involve human subjects***. The conditional approval is pending receipt of the following information, clarification, and modifications:

1. Recruitment Letter from School District.
   a. First paragraph. Explain the term "anonymous" or include "in that no identifying information will be gathered" immediately following the use of the word "anonymous".
   b. Include a sentence explaining that participation in the survey is no indication of drug use, and that all children in the 6th and/or 10th grades will have an equal chance of being contacted.
   c. Time needed to complete the survey. Resolve discrepancy between the time indicated in the recruitment letter and script (one states 30 minutes and the other 20 minutes estimated to complete the survey).
   d. Modify and "bold" the next to the last sentence in the letter to read: "**Your child may or may not be called, but if you do not want your child to have a chance of participating, please contact your school by [date].**"
   e. Include contact information for the researcher and the DHS IRB (Mary Caputo 801 538-4295).
2. Script for Telephone Survey.
   a. Should any participants have questions concerning the survey or their rights to respond to the survey, refer them back to the recruitment letter, or provide researcher and DHS IRB contact information if they no longer have that letter (same as 1.d. above).
   b. Include risk/benefit information for parents and participants: e.g. "the risk to your child is that they may be uncomfortable discussing these issues", and "there are no direct benefits to your child, but it will help your school direct drug prevention/planning services".

c. Although stated in the recruitment letter, restate or re-emphasize the voluntary nature of participation, and that participants may refuse to answer any or all of the questions asked. You may wish to simply re-state the 4 items outlined in the recruitment letter.
d. Modify the script to parents to include a prompt or request that child be allowed some privacy in responding to the survey questions.
e. Modify the script to children to ask if they have sufficient privacy to allow them to respond to the survey questions.

3. Provide copy of final survey instrument (formatting was scrambled in copy provided).

Please provide the above-requested information to Mary Caputo, DHS IRB Chair, at 120 North 200 West, Room 221, Salt Lake City, Utah 84103. Upon receipt of such verification, we will issue a letter with our final approval decision, which will allow you to fully implement your research.

If you need further assistance, please call Ms. Caputo at 538-4295.

Sincerely,

Mark E. Ward, Deputy Director
Department of Human Services

cc: Division IRB Representative, Agency
Mary Caputo, DHS IRB

DATA EXCLUSION VERIFICATION

TO: Name, Department

FROM: Mary Caputo, Chair, Department of Human Services Institutional Review Board (DHS IRB)

OR

Name of Division Representative, Division Name

DATE: February 22, 2000

RE: DHS IRB approval lapse

The DHS IRB approval for your application entitled, "_____(Title)_____" was inactive from January 18, 2000 through January 19, 2000. As you are aware, no work may take place on studies without an active IRB approval. For our records, please sign in the space provided below indicating which of the two situations have taken place and **return to my attention by _____.** Please contact me at mcaputo@utah.gov or 801-538-4295 if I can answer any questions. Thank you for your prompt attention to this matter.

☐ All data collected and/or analyzed on the above named application during said period of time **has been discarded** and will not be included in the study.

_____ _____
Name Date

☐ **No data collection and/or analysis** took place on said application during the time period listed above.

_____ _____
Name Date

cc: DHS IRB Chair or DHS Division Representative (depending on who sends)
College/University Advisor or Chair Name, Dept.

Checklist for Division-Level Approval of Research Proposal

UTAH DEPARTMENT OF HUMAN SERVICES

(This form may be used as the Division's Letter of Support of a Research Proposal being submitted for Human Rights Committee review and/or may be used for Division approval of research only requiring only Division review and approval.) If a study involves more than minimal risk and no direct benefit to the subject, attach a separate justification statement. ***A copy of the completed form must also go to the Human Rights Committee Chair.***

Date of Review:_____
Researcher's Name:_____
Address:_____
Work Phone:_____ Home Phone:_____
Start Date: _____ Anticipated End Date: _____

1. TITLE AND NATURE OF STUDY:

2. REVIEWED FOR THE FOLLOWING:

_____ (a) the research is in the best interests of the Division and the Division's clients;

_____ (b) the researcher has made adequate provision for obtaining all required informed consents and informed assents;

_____ (c) the research protocols and procedures are designed to protect individual privacy and ensure confidentiality, respect, and ethical treatment during the researcher's gathering of the data, storage and retrieval of the data, and publication of the data;

_____ (d) the research study involves no more than minimal risk* to subjects, or the direct benefits to the subjects outweigh the risks;

_____ (e) the research methodology is sufficiently sound to yield results that offer a potential benefit to the Department or the Division; and

_____ (f) the research protocol protects individual privacy rights and complies with the Department's Vision and Mission Statements, the Department Code of Ethics and any applicable rules or statutes, including UCA § 63-2-202 (8).

3. RECOMMENDATION FOR APPROVAL: Yes _____ No _____

Division Representative: _____ Date: _____

Division Director: _____ Date: _____

_____

[1] According to 45 CFR § 46.102 (i), "Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests."

EXEMPT LETTER

Date

PI Name and Degree/Title
University of _____, College of _____
Address
City, STATE Zip

Subject: Title of Research, DHS IRB # _____, **Exempt Research**

Dear Dr. _____:

Based on the expedited review and recommendation by (Division Representative), Division _____(____), we have found your proposed study to be exempt from the Department of Human Services Institutional Review Board (DHS IRB) review. The exemption is pursuant to 45 CFR 46.101(b)(4) and is based on the fact that you seek de-identified aggregate data that has been generated by the Division _____ (____) and is publicly available.

In the event that any changes are made to the research following this determination (e.g., changes that may include acquisition of data which is not publicly available or may identify DHS clients, etc.), please document these changes on the attached and send it to the DHS IRB.

If you need further assistance, please call (Division Representative) at 538-#### or you may call me at 538-4295. Once your research is completed, please send us a copy of your final report so the Division of Youth Corrections and the clients they serve may benefit from the findings of your research.

Sincerely,

Mary M. Caputo, Chair
DHS Institutional Review Board

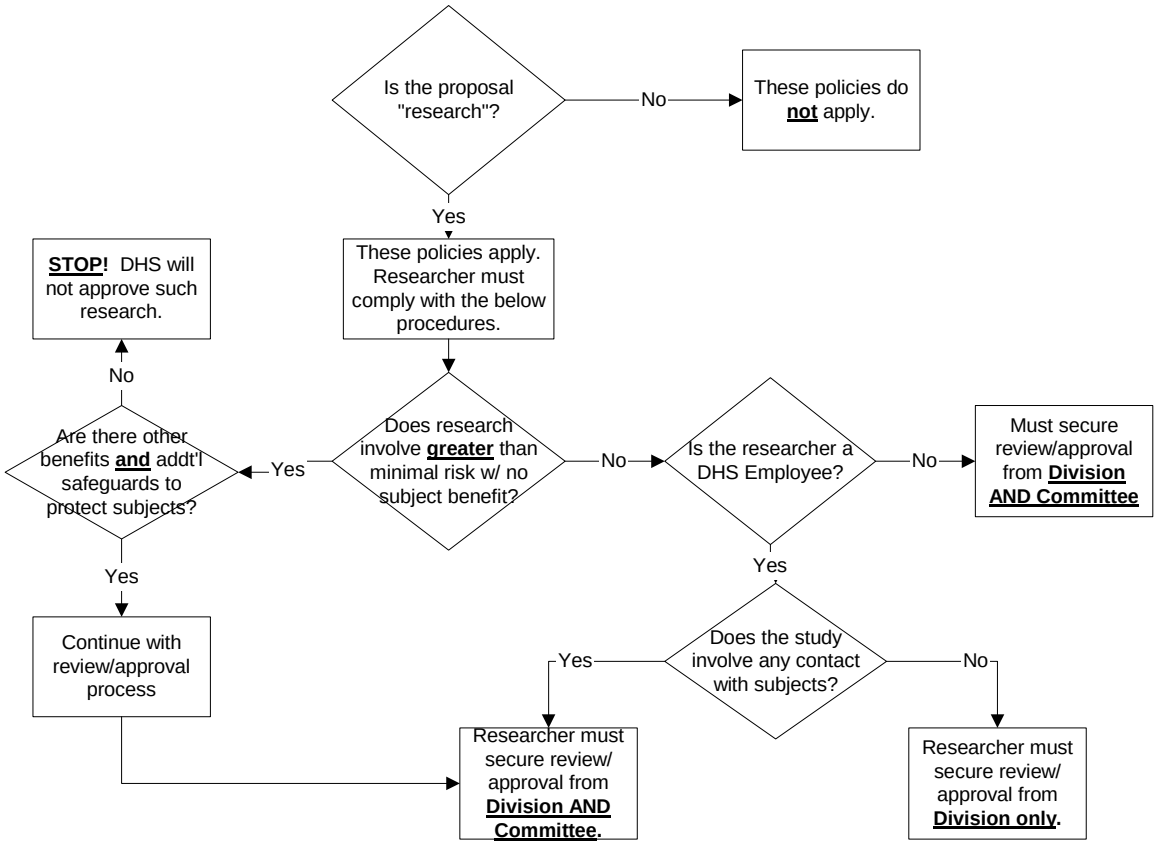
Attachment

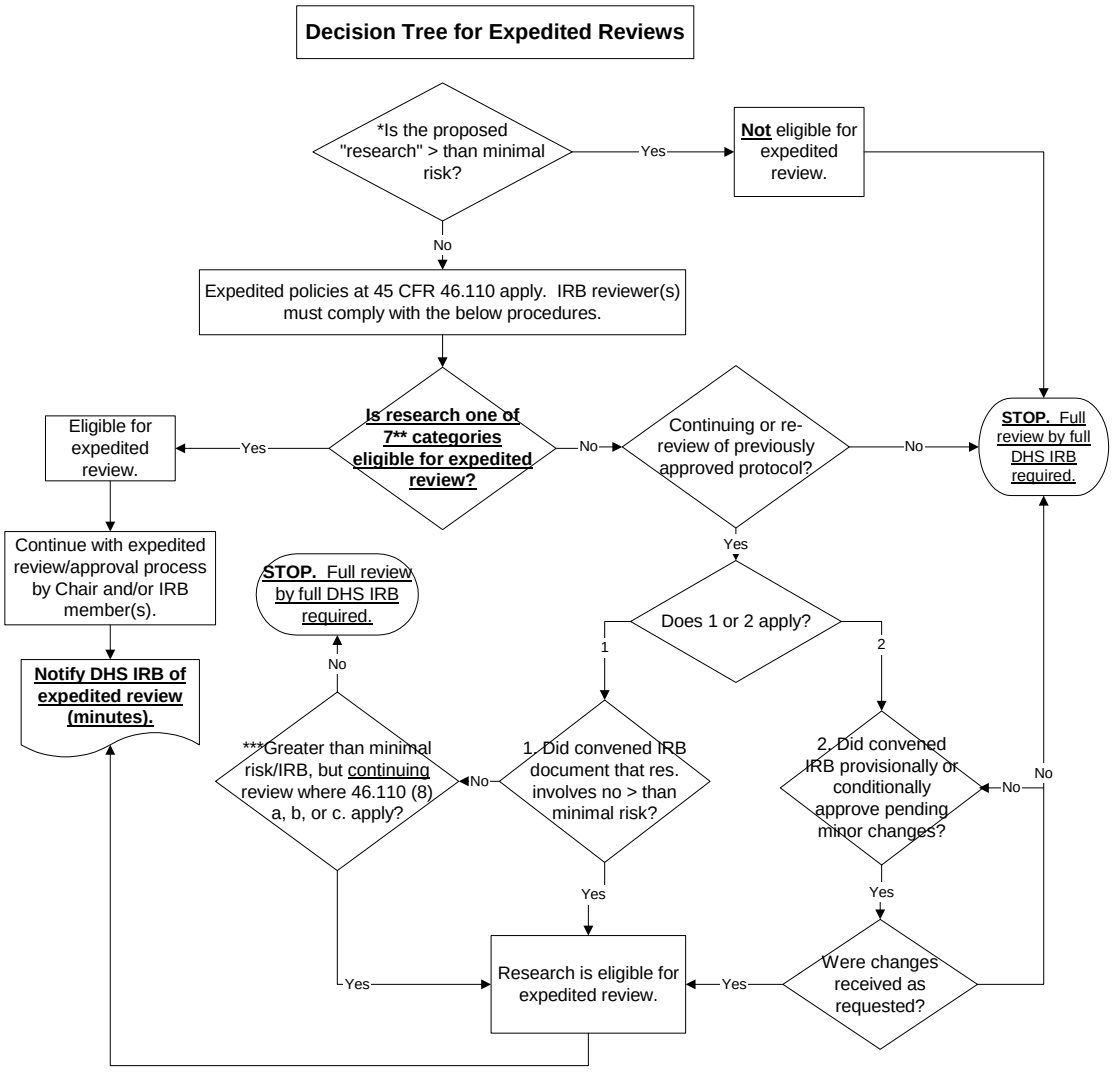
cc: Mark E. Ward, DHS EDO
Division Representative

APPENDIX D

DECISION TREES

Level of IRB Review





* As determined by Division Representative (may consult IRB Chair, if needed).

** IT IS BEST TO REFER TO THE FULL TEXT AT 45 CFR 46.110

(1) Clinical studies for which: a) investigational new drug application not required, or b) medical devices which (i) investigational device exemption not required; or (ii) the device is approved for marketing.

(2) Collection of blood samples from: a) healthy nonpregnant adults weighing 110 or >; b) other adults/children considering wgt, health of subjects, collection procedure, amt of blood to be collected (not to exceed 50 ml or 3 ml per kg in 8 wk period).

(3) Prospective collection of biological specimens by noninvasive means; e.g. hair/nail clippings, saliva, excreta , etc.

(4) Data collected thru noninvasive means (excluding x-ray or microwaves, & not involving general anesthesia or sedation,); e.g., MRI, EKG, etc.

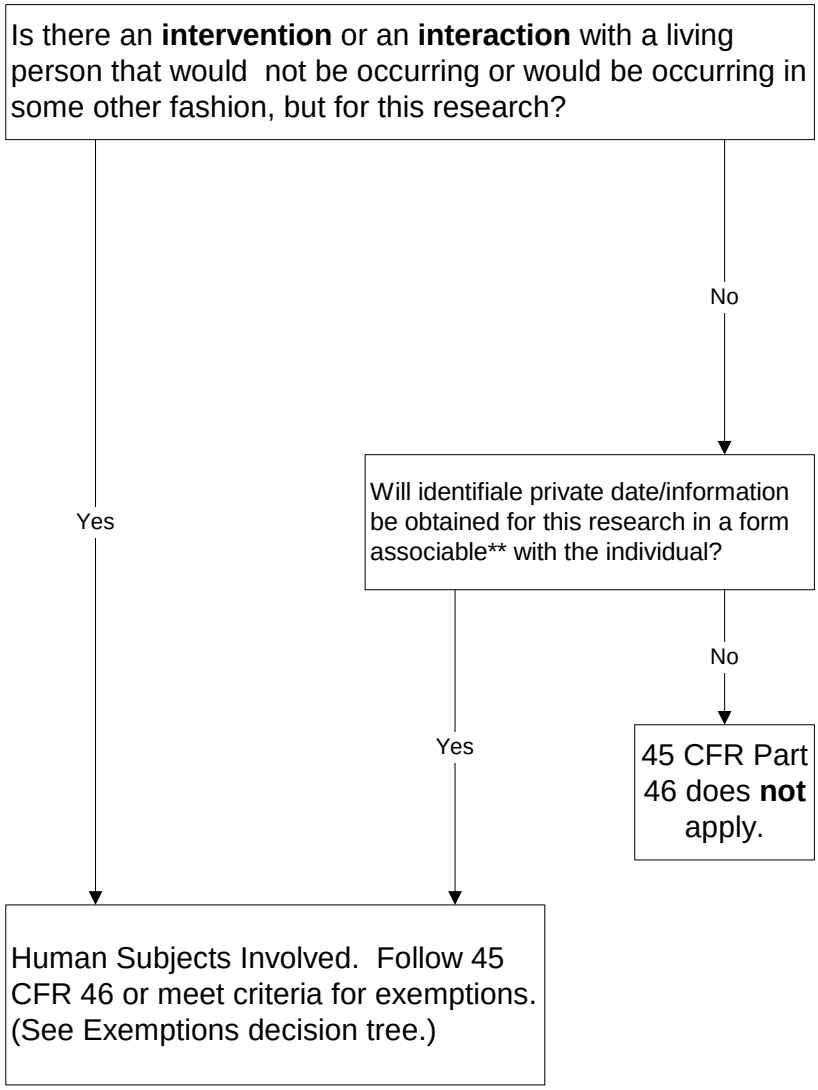
(5) Materials (data, documents, records, or specimens) collected, or will be collected solely for nonresearch purposes; i.e., medical treatment or diagnosis.

(6) Collection of data from voice, video, digital, or image recordings made for research purposes.

(7) Individual or group characteristics or behavior, or research using survey, interview, oral history, focus group, program evaluation, human factors evaluation, or QA methodologies.

***(8) Continuing review: a) where (i) closed to new enrollments; (ii) subjects completed all research-related interventions; & (iii) open only for long -term follow-up of subjects; or b) no subjects enrolled & no addt'l risks identified; or c) remaining work limited to data analysis.

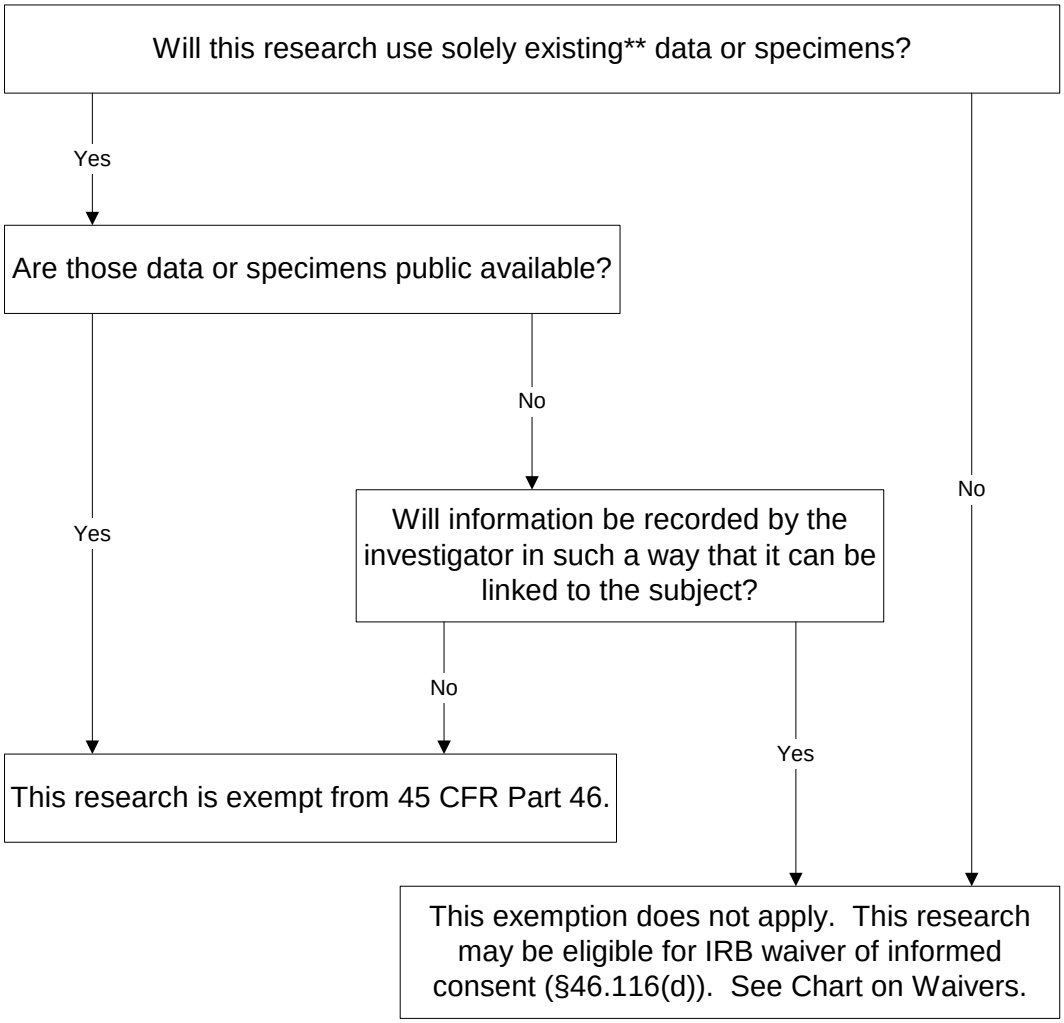
Is definition of "human subject" at §46.102(f) met in this research activity?*



* Decision tree from OHRP guidance documents.

**"Associable" means the identity of the subject is or may readily be ascertained or associated with information or data.

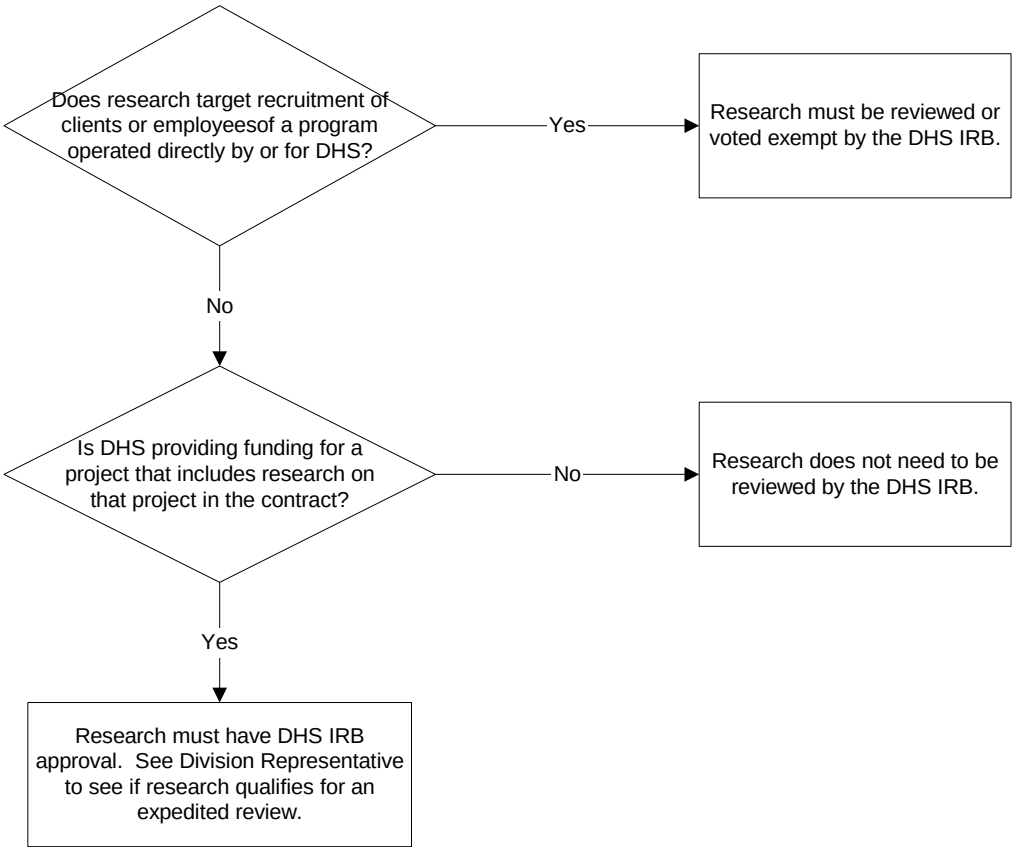
Exempt Decision Tree
to determine if research is exempt in accordance with
§46.101(b)(4)*



*Decision charts from OHRP Guidance documents at ohrp.osophs.dhs.gov/humansubjects/guidance/decisioncharts.htm.

**"Existing" means collected (i.e., on the shelf) prior to the research for a purpose other than the proposed research. It includes data or specimens collected in research and nonresearch activities.

Decision Tree for Contract Agency Research



Waiver or Alteration of Informed Consent Under §46.116(d)
(to waive informed consent or alter informed consent elements)